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Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority Pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information form Agency files and Program Offices. This addendum is to update the existing Ambient Water Quality Criteria Document for Aldrin/Dieldrin.

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ADDENDUM FOR ALDRIN/DIELDRIN

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OFFICE OF WATER REGULATIONS
AND STANDARDS

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PREFACE

Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information from Agency files and Program Offices. The first draft of this addendum was prepared by Syracuse Research Corporation under contract no. 68-C8-0004.

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LIST OF ABBREVIATIONS

BCF	Bioconcentration factor
CRAVE	Carcinogen Risk Assessment Verification Endeavor
K_{ow}	Octanol/water partition coefficient
LOAEL	Lowest-observed-adverse-effect level
NOAEL	No-observed-adverse-effect level
PEL	Permissible exposure limits
ppm	Parts per million
RfD	Reference dose
TLV	Threshold limit value
TWA	Time-weighted average

INTRODUCTION

Under Section 304(a)(1) of the Clean Water Act of 1977 as amended in 1987, the U.S. EPA is required to publish criteria for water quality accurately reflecting the latest scientific knowledge regarding the effects on health and welfare that may occur from the presence of pollutants in any body of water, including groundwater. In accordance with the 1977 act, Ambient Water Quality Criteria Documents (AWQCDs) were developed in 1980 for 65 toxic pollutants or classes of pollutants listed under Section 307(a)(1).

These addenda are intended to serve as an update of the original AWQCDs. The addenda provide the Agency with the latest scientific assessments of potential health hazards associated with these pollutants and serve as guidelines for modifying the current (1980) AWQCDs.

The human health criteria in these addenda are based on Agency verified risk assessment values when available. These values consist of reference doses (RfD) for those chemicals believed to be systemic toxicants (i.e., do not induce cancer) and cancer risk factors for those thought likely to cause cancer in humans. The verification process consists of a review and consensus of risk assessment values provided by an Agency workgroup consisting of scientists from each of the major Agency offices. Assessments for noncarcinogens are verified by the RfD workgroup and those for carcinogens are verified by the Carcinogen Risk Assessment Verification Endeavor (CRAVE) workgroup. If such values are not available, the criteria are based on the most recent Agency health assessment. In the absence of any appropriate Agency value, RfD values or cancer risk factors are derived by current Agency methods if adequate new data are available, and criteria are recommended based on the proposed RfD or risk factor.

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is derived by dividing a NOAEL or LOAEL for subchronic or chronic exposure by standard uncertainty factor(s) times an additional uncertainty factor:

$$RfD = \frac{\text{NOAEL or LOAEL}}{UF(s) \times UF}$$

The standard uncertainty factors are applied to reflect the various types of data used to estimate RfDs. An uncertainty factor of 10 is used to account for variations in human sensitivity when extrapolating from valid human studies involving long-term exposure of average, healthy subjects. An additional 10-fold factor is used for each of the following: to extrapolate from long-term animal studies to the case of humans, to extrapolate from subchronic animal studies to chronic exposure, and to extrapolate from a LOAEL to a NOAEL. An additional uncertainty factor of >0-10 may be applied to reflect professional assessment of the uncertainties of the study and data base not explicitly addressed by the standard uncertainty factors (i.e., completeness of the overall data base). The default value for the additional uncertainty factor is 1.

In assessing the carcinogenic potential of a chemical, the U.S. EPA classifies the chemical into one of the following groups according to the degree of evidence in epidemiological studies and animal studies: Group A - Human Carcinogen; Group B - Probable Human Carcinogen [limited evidence in humans with or without sufficient evidence in animals (Group B1) or inadequate evidence in humans with sufficient evidence in animals (Group B2)]; Group C - Possible Human Carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); Group D - Not Classifiable as to

Human Carcinogenicity (inadequate or no evidence); Group E - Evidence of Noncarcinogenicity for Humans. Quantitative carcinogenic risk assessments are performed for chemicals in Groups A and B, and on a case-by-case basis for chemicals in Group C. Upper-bound cancer unit risks (slope values) are estimated through the use of mathematical extrapolation models. Most commonly for animal data, the linearized multistage model with a 95% upper confidence limit is used to provide a low-dose estimate of cancer risk. The cancer risk is characterized as an upper-limit estimate (i.e., the true risk to humans, while not identifiable, is not likely to exceed the upper-limit estimate and in fact may be lower). Alternative risk models to the multi-stage model, such as the one-hit, Weibull, Logit or Probit model, are available and may be used when the evidence indicates that they may be more appropriate. In the absence of such evidence, the Agency recommends the linearized multistage model to provide consistency of approach and an upper-bound on the potential carcinogenic risk. In the case where human data are used for quantitative risk assessment, an upper-bound estimate rather than a 95% upper-bound estimate is used when low-dose linearity is assumed.

In the development of this Addendum to the AWQCD on aldrin/dieldrin, recent Agency assessments have been consulted. A computerized literature search was conducted to cover studies published more recently than the latest Agency assessment (i.e., published in 1986 to 1988). New key studies have been evaluated.

REVIEW OF NEW DATA

Toxicologic/Carcinogenic Effects

U.S. EPA (1987e) recently re-evaluated carcinogenicity data for aldrin. Negative results were obtained in three carcinogenicity studies with Osborne-Mendel rats (Deichmann et al., 1970; Fitzhugh et al., 1964; NCI, 1977). In contrast, the NCI (1977) study using mice yielded positive results as did the Davis (1965) and Davis and Fitzhugh (1962) studies. Since U.S. EPA (1980, 1987a) concluded that mice appear to be the species most susceptible to the carcinogenic effects of aldrin, the negative rat studies will not be discussed further in this document; however, detailed discussions of these studies are presented in U.S. EPA (1980, 1987a,e).

In the NCI (1977) mouse study, groups of 50 male and 50 female B6C3F1 mice were fed diets containing 3 or 6 ppm (females) or 4 or 8 ppm (males) aldrin for 80 weeks followed by a 10- to 13-week observation period. Matched controls consisted of 10 females and 20 males; pool controls consisted of 79 females and 92 males from other experiments (all controls were untreated). There was a significant dose-related increase in the incidence of hepatocellular carcinomas in male mice [matched controls 3/20, pooled controls 17/92, low-dose 16/49, high-dose 25/45 ($p<0.001$)]. NCI (1977) concluded that aldrin was carcinogenic to male mice, causing hepatocellular carcinomas.

The feeding study of Davis (1965) as reported in Epstein (1975) was also re-evaluated. In this study, C3H mice (100/sex) were exposed to 0 or 10 ppm aldrin (purity unspecified) in their diet for 2 years. The survival rate in the treated group was reduced compared with the control group; however, data were not broken down by sex or time of death. The incidence of hepatic

hyperplasia and benign hepatomas in the aldrin-treated mice was approximately double that of the controls, whereas the number of hepatic carcinomas was about the same. A reevaluation of this data by Dr. Reuber concluded that most of the benign hepatomas were carcinomas (Epstein, 1975). The incidence of hepatocarcinogenicity was 2/53 and 72/85 for control and treated females, and 22/73 and 75/91 for control and treated males, respectively. Although this study did not provide a detailed pathologic examination, the evidence for an oncogenic respone was considered substantial.

Davis and Fitzhugh (1962) reported a previous 2-year feeding study in mice in which 215 C3HB/Fe mice were given 10 ppm aldrin (purity not specified). Controls consisted of 217 mice. Mice that died during the experiment, as well as all 2-year survivors, were necropsied (U.S. EPA, 1987a). Average survival of the treated mice was ~2 months less than controls; however, intercurrent diseases, pneumonia and intestinal parasitism were present and may have influenced the long-term survival rate. Combined results for both sexes indicated a statistically significant ($p<0.001$) increase in the incidence of hepatomas (hepatic cell adenomas). An independent evaluation of the liver lesions by Dr. Reuber, as reported in Epstein (1975), concluded that most of the hepatomas were liver carcinomas.

Carcinogenicity data for dieldrin were also re-evaluated recently (U.S. EPA, 1987b). Of the 13 bioassays judged adequate for assessment of carcinogenicity, 9 were previously reviewed by U.S. EPA (1987c). Subsequent to the original derivation of the ambient water quality criteria, two carcinogenicity studies of dieldrin were published. Tennekes et al. (1981) conducted a 110-week study in which weanling male CF1 mice were given 0 or 10 ppm dieldrin in the diet. While the results of this study are complicated by the use of two different types of diet and two types of bedding, the

administration of dieldrin did result in a clear positive increase in hepatic tumors. Nodular hepatic lesions were first observed in a mouse at 43 weeks of age. At 65 weeks, the liver tumor incidence was 5% (3/60; all adenomas) in controls and 81% (48/59; 33 adenomas/15 carcinomas) in treated mice. By 110 weeks, the incidence was 10% in controls and still 81% in treated mice, but there was a major difference in the number of hepatocellular carcinomas (39% in treated, 1% in controls) and the number of lung metastases (14% vs. 0%). These results were highly significant ($p<0.01$) and represented a substantial carcinogenic response.

In the second study, Meierhenry et al. (1983) administered 10 ppm dieldrin (98% pure) to three strains of male mice (C57Bl/6J, C3H/He and B6C3F1) in the diet for 85 weeks. At least three mice were necropsied 8 weeks after the experiment began and at intervals $\leq$132 weeks of age. Significantly ($p<0.01$) increased incidences of hepatocellular carcinomas were seen in treated groups of all three strains. The number of treated mice that developed hepatocellular carcinomas was significantly higher in C3H (19/50) and B6C3F1 (26/62) than in the C57Bl (21/71) treated mice.

A summary of all studies deemed useful for risk assessment for dieldrin (U.S. EPA, 1987b) are presented in Table 1. No sex or strain specificity of carcinogenicity was noted in mice in these studies. Human q_1^* values were estimated using the linearized multistage model (U.S. EPA, 1987c).

Bioconcentration Factor (BCF)

In deriving the ambient water quality criteria (U.S. EPA, 1980), a weighted BCF of 28 was used for aldrin while a BCF of 4670 was used for dieldrin. The BCF for dieldrin was based on experimental data. However, no useful measured BCF could be obtained for aldrin because it is rapidly converted to dieldrin by aquatic organisms. Also, exposure of aquatic

TABLE 1

Dose-Response Data For Hepatocellular Carcinoma In Mice
Treated Orally with Dieldrin*

Strain/Sex	TWA Dose (mg/kg/day)	Tumor Incidence	q_1^* $(mg/kg/day)^{-1}$	Reference
C3H/male	0.0 1.3	22/73 62/71	22	Davis, 1965
C3H/female	0.0 1.3	2/53 62/71	25	Davis, 1965
CF1/male	0.000 0.013 0.13 1.3	58/288 32/124 34/111 165/176	25	Walker et al., 1972
CF1/female	0.0013 0.013 0.13 1.3	39/297 24/90 32/87 136/148	28	Walker et al., 1972
CF1/male	0.00 0.16 0.33 0.65 1.3 2.6	9/78 6/30 13/30 26/30 5/11 12/17	15	Walker et al., 1972
CF1/female	0.00 0.16 0.33 0.65 1.3 2.6	8/78 5/30 12/28 18/30 9/17 8/21	7.1	Walker et al., 1972
CF1/male	0.00 1.3	11/45 30/30	55	Thorpe and Walker, 1973
CF1/female	0.00 1.3	10/44 26/30	26	Thorpe and Walker, 1973
B6C3F1/male	0.000 0.325 0.65	17/92 12/50 16/45	9.8	NCI, 1977

TABLE 1 (cont.)

Strain/Sex	TWA Dose (mg/kg/day)	Tumor Incidence	q_1^* $(mg/kg/day)^{-1}$	Reference
CF1/male	0.00 1.3	25/252 113/139	18	Tennekes et al., 1981
C57B1/6J/male	0.00 1.3	0/69 21/71	7.4	Meierhenry et al., 1983
C3H/He/male	0.00 1.3	6/50 19/50	8.5	Meierhenry et al., 1983
B6C3F1/male	0.00 1.3	3/76 26/62	11	Meierhenry et al., 1983

*Source: U.S. EPA, 1987b,c

organisms to aldrin is low because it is converted to dieldrin in soil. The BCF of 28 for aldrin was obtained mathematically using measured values for the octanol-water partition coefficient. However, a more recent review (U.S. EPA, 1987a) listed a BCF of 10^{-3} to 10^{-4} for various aquatic organisms. Therefore, in developing the new ambient water quality criteria, a BCF of 4670 will be used for both aldrin and dieldrin until newer information is available.

QUANTIFICATION OF EFFECTS

The ambient water quality criteria for consumption of water and fish and shellfish for aldrin of 0.0074, 0.074 and 0.74 ng/ℓ and those for dieldrin of 0.0071, 0.071 and 0.71 ng/ℓ corresponding to lifetime increased cancer risk levels of 10^{-7}, 10^{-6} and 10^{-5}, respectively, were based on chronic feeding studies with mice (U.S. EPA, 1980). The criteria for aldrin were derived using parameters for both aldrin and dieldrin because of biotransformation and the conversion of aldrin to dieldrin in the environment. These parameters include the aldrin q_1^* of 11.45 $(mg/kg/day)^{-1}$, which was derived from liver carcinoma data of B6C3F1 male mice exposed to dietary aldrin in an NCI bioassay (NCI, 1977; U.S. EPA, 1980). A q_1^* of 30.37 $(mg/kg/day)^{-1}$ for dieldrin was estimated by a linearized multistage procedure, based on liver carcinoma incidences in the chronic feeding study with female CF1 mice (Walker et al., 1972). Other parameters used include a very low K_{ow}-based BCF of 28 for aldrin and an experimentally determined BCF for dieldrin of 4670. Criteria for consumption of fish and shellfish only were also derived (e.g., 0.76 ng/ℓ for dieldrin and 0.79 ng/ℓ for aldrin for an increased risk level of 10^{-5}). The calculations of the ambient water quality criteria for aldrin were carried out as usual, but included two terms for exposure through the ingestion of fish. One term was based on the BCF and q_1^* for aldrin and the other was based on the BCF and q_1^* for dieldrin. The rationale for this was that aldrin is extensively metabolized to dieldrin. The actual calculations of the criteria are described in detail in the AWQCD (U.S. EPA, 1980).

More recently, a broader range of data were considered (see previous section) for revising human carcinogenicity potency factors for aldrin (U.S. EPA, 1987e) and dieldrin (U.S. EPA, 1987b), again using the data for the most sensitive experimental animal systems examined (i.e., hepatocellular carcinomas following dietary exposure of several strains of mice). The classification of aldrin and dieldrin as B2 carcinogens (probable human carcinogens) was confirmed based on the adequate evidence of carcinogenicity of both aldrin (U.S. EPA, 1988) and dieldrin (U.S. EPA, 1987b) in mice and inadequate evidence in humans. In dietary bioassays, aldrin was carcinogenic to three strains of mice, whereas dieldrin, a metabolite of aldrin, was carcinogenic to several strains of mice. Less extensive studies suggested that other species, including rats, dogs, hamsters and monkeys, are much less susceptible than mice to the carcinogenic effect of aldrin or dieldrin.

A human q_1^* of 17 $(mg/kg/day)^{-1}$ for aldrin was derived (U.S. EPA, 1987e) as a geometric mean of three estimates ranging from 12-23 $(mg/kg/day)^{-1}$ based on dose-response data for liver carcinomas in mice fed aldrin (Davis, 1965; Epstein, 1975; NCI, 1977).

For dieldrin, the new potency factor of 16 $(mg/kg/day)^{-1}$ was derived (U.S. EPA, 1987b) as a geometric mean of 13 estimates, ranging from 7.1-55 $(mg/kg/day)^{-1}$ (see Table 1), from dose-response data for liver carcinomas in mice fed dieldrin (Davis, 1965; Walker et al., 1972; Thorpe and Walker, 1973; NCI, 1977; Tennekes et al., 1981; Meierhenry et al., 1983).

Using the verified potency factor of 17 $(mg/kg/day)^{-1}$ for aldrin and 16 $(mg/kg/day)^{-1}$ for dieldrin, and assuming a 70 kg body weight and a daily intake of 2 ℓ of water and 6.5 g of fish and shellfish with a common

BCF of 4670 for both chemicals, the proposed new criteria for aldrin and dieldrin in ambient water are as follows:

ALDRIN:

Exposure Assumptions (per day)	Risk Levels and Corresponding Criteria (ng/ℓ)				
	0	10^{-7}	10^{-6}	10^{-5}	10^{-4}
2 ℓ of drinking water and consumption of 6.5 g of fish and shellfish	0	0.013	0.13	1.3	13
Consumption of fish and shellfish only	0	0.014	0.14	1.4	14

DIELDRIN:

Exposure Assumptions (per day)	Risk Levels and Corresponding Criteria (ng/ℓ)				
	0	10^{-7}	10^{-6}	10^{-5}	10^{-4}
2 ℓ of drinking water and consumption of 6.5 g fish and shellfish	0	0.014	0.14	1.4	14
Consumption of fish and shellfish only	0	0.014	0.14	1.4	14

EXISTING STANDARDS AND CRITERIA

ACGIH (1987) recommended TWA-TLV values of 0.25 mg/m^3 for both aldrin and dieldrin with a skin notation. These are identical to PELs issued by OSHA (1985).

An inhalation slope factor of 17 (mg/kg/day)$^{-1}$ for aldrin based on the oral data has been verified by the EPA Agency-wide CRAVE committee and is available on IRIS (U.S. EPA, 1987e), which also lists an inhalation unit risk of 4.9×10^{-3}/µg/m^3.

The U.S. EPA (1985) verified an aldrin RfD of 3×10^{-5} mg/kg/day for noncarcinogenic health effects from oral exposure.

An oral RfD for dieldrin of 5×10^{-5} mg/kg/day has been verified by the U.S. EPA (1987d).

An RQ of 1 pound has been proposed for aldrin based on its aquatic toxicity and potential carcinogenicity (U.S. EPA, 1986).

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